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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/153,838 09/15/98 WILS

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EXAMINER

KETTER, J

ART UNIT

PAPER NUMBER

1636

12

DATE MAILED:

09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

— SEE ATTACHED —

Office Action Summary

Application No.

09/152,838

Applicant(s)

Wils et al.

Examiner

J. KETTER

Group Art Unit

1636

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/19/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 25 A~O 26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Claims 1-22 are allowed. This non-final Office Action is being sent in response to the Brief on Appeal filed 19 July 2000, reopening prosecution on the merits to include the new grounds of rejection under 35 USC § 102, supra. The delay in reconsidering the disclosures in the specification and the relationship of such to the exact nature of the claimed invention are regretted.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 25 and 26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Woodard et al. (A), for reasons of record set forth in papers Nos.2 and 6, mailed 23 November 1998 and 17 August 1999, respectively.

At page 3 of the Brief, Applicants argue that Woodard et al. does not teach removal of chromosomal DNA. However, as set forth in the previous Office Action, at column 1, lines 12-33, it is taught that the method is useful for isolating plasmids. To isolate a plasmid means to remove all non-plasmid DNA, including chromosomal DNA. The fact that lambda bacteriophage

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was exemplified does not negate the teachings at column 1 of plasmid isolation. Applicants argue further, that no teaching of pharmaceutical grade DNA is provided in Woodard et al. However, the highly pure plasmid DNA resulting from conventional purification methods such as Woodard et al. discloses, would be deemed pharmaceutical grade. "Pharmaceutical" is merely one description for highly purified plasmid DNA. Other reasons for such purity exist. Indeed, Applicants do not even claim a pharmaceutical composition, and the purity of the composition as claimed is defined by means other than pharmaceutically. Applicants argue further, that Woodard et al. is silent about the endotoxin content. However, as set forth in previous Office Actions, the low level of endotoxin would inherently result from the conventional purification methods disclosed by Woodard et al. At the Abstract, Woodard et al. even states, with respect to DNA bound to the disclosed column, that the column material "is washed to remove *all* cellular components other than DNA which are [*sic*] bound to the material" [*italics added*]. Thus, it is reasonable to assert that the DNA produced by Woodard et al. is of such high purity as to be free from all non-DNA components, thus inherently meeting the limitations of the instant claims.

Claims 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by the prior art as admitted by Applicants.

At pages 1 and 2 of the specification, Applicants teach that conventional laboratory methods of producing plasmid DNA for pharmaceutical purposes were inadequate because said methods could not be scaled up readily. For example, see the fourth paragraph at page 1, wherein

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Applicants state "[t]wo of these laboratory methods are those which are most frequently employed and which give the best results." At the second full paragraph at page 2, Applicants go on to criticize these methods, not for the presence of endotoxins or chromosomal DNA, but rather for the use and possible residue of ethidium bromide and enzymes of animal origin. However, these contaminants are not excluded from the claimed compositions. As such, Applicants' comparison of the advantages of the disclosed and claimed ceramic hydroxyapatite method (which remain patentable) with older, slower, and smaller scale methods in the prior art, is understood to be a tacit admission that said older methods produced the same product, however less easily.

Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR § 1.6(d)). The Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant *does* submit a paper by fax to this number, the examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the examiner, with such faxed papers being handled in the manner of mailed responses. Applicants are encouraged to use the latter two fax numbers unless immediate action by the

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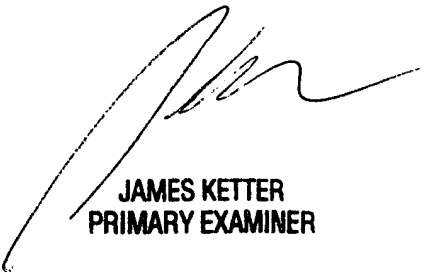
examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner can normally be reached on Monday-Thursday from 8:00 AM-5:30 PM, and on alternate Fridays.

If attempts to reach the Examiner are unsuccessful, the Examiner's supervisor, George Elliott, can be contacted at (703) 308-4003.

James Ketter

September 25, 2000



**JAMES KETTER
PRIMARY EXAMINER**